



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,999	11/13/2001	Michael Birsha Davies	PG3619USW	7801
23347	7590	05/01/2007	EXAMINER	
GLAXOSMITHKLINE			BROWN, MICHAEL A	
CORPORATE INTELLECTUAL PROPERTY, MAI B475			ART UNIT	
FIVE MOORE DR., PO BOX 13398			PAPER NUMBER	
RESEARCH TRIANGLE PARK, NC 27709-3398			3772	
			MAIL DATE	DELIVERY MODE
			05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/914,999

Applicant(s)

DAVIES, MICHAEL BIRSHA

Examiner

Michael Brown

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-8, 11-25, 27, 28 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, 11-25, 27-28 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6-8, 11-17 and 19-25, 27-28 and 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Wetterlin.

Wetterlin discloses in figures 1-3 an inhaler comprising a housing 6, defining an airway 5, a (pre-meter or discrete, col. 3, line 2, the dose is pre-metered because the amount that will be released has already been determined), dose of medicament (inside container 12), a dose protector 4, covering means 18, that is biased into contact with the container 12, and opens in response to one condition (air coming through 5) in a first direction (upward), but not in a second direction, the covering means opens in response to air, the covering means responds by covering the dose when air flows in a second direction (which could be caused by a user exhaling into the inhaler), the covering means is a sealing flap (a membrane, made of plastic) and the dose is metered by volume of the medicament or by the volume of the container (col. 3, lines 4-8).

As for claims 13-17, 19-25, 27-28 and 30-31, Wetterlin discloses an inhaler comprising a housing 12, defining an airway 11, a pocket 12, (the word pocket is being interpreted as an area used to store something), in the form of a blind cavity having a sole open end (at 11) containing pre-metered dose of medicament, the housing includes a sealing flap 18, the container has a rim (around the opening 11), the sealing flap is spaced from the pocket (fig. 1), a closure means 10, the distance between the inside walls increase (moving downward from 11) as the distance from the pocket increase (moving downward from the top of 11), a fixed seal 8, the inhaler is a dry powered inhaler (col. 1, lines 20-21) and a method of administering a dose of medicament. The inhaler disclosed by Wetterlin is a unit dose inhaler with a pre-metered dose of medicament.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wetterlin in view of Leedom.

Wetterlin discloses in figures 1-3 a dose protector, substantially as claimed. However, Wetterlin doesn't disclose the sealing flap being a thermosetting rubber. Leedom teaches in figure a dose protector comprising a sealing flap made of a shape memory material. It would have been obvious to one having ordinary skill in the art at the time

that the invention was made that the sealing flap made of plastic disclosed by Wetterlin could be fabricated of a thermosetting rubber because it is a shape memory material that would close the air off and prevent the flow when the user desires.

Response to Arguments

Applicant's arguments filed January 5, 2007 have been fully considered but they are not persuasive. Applicant argues that Wetterlin doesn't disclose a pre-metered dose in the inhaler. However, the amount of medicament released in Wetterlin is pre-metered based on the size of the container. If an individual needs all of the medicament for one dose, that amount is predetermined by the size of the pocket (the inside of 12). If a small amount of medicament is desired that amount is still pre-metered based on the size of the opening from the container and based on the amount in the container. Applicant argues that the chamber 20 has two openings. However, the pocket is now being interpreted as the inside of container 12. The container has a blind opening 11 and it is the sole opening. Applicant argues that Wetterlin isn't a dose unit. However, the phrase dose unit is so broad that Wetterlin can be interpreted as a dose unit.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 3772

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 571-272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Brown
April 27, 2007



MICHAEL A. BROWN
PRIMARY EXAMINER